

Application No. 10/034,950
Amendment and Response dated November 15, 2006
In Response to May 15, 2006 Office Action

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1-83 (Canceled)

84. (Previously Presented) A crystal of Infliximab.

85. (Currently Amended) A pharmaceutical composition comprising an-a whole antibody crystal wherein said antibody concentration is greater than about 20 mg/ml.

86. (Currently Amended) A large-batch crystallization method for crystallizing an antibody comprising the following steps:

a. preparing a series of different micro-batch crystallization solutions each of a total volume of at least 33 μ l, each solution comprising the antibody and a different crystallization buffer;

b. crystallizing the antibody from each of the micro-batch crystallization solutions;

c. selecting a micro-batch crystallization solution from the series of solutions that produces antibody crystals of good quality and yield;

d. preparing a large-batch crystallization solution comprising the antibody and the crystallization buffer that characterized the selected micro-batch crystallization solution; and

e. agitating the large-batch crystallization solution for between about 3 and about 48 hours at a temperature between about -21°C and about 61°C, to produce antibody crystals.

87. (Previously Presented) The large-batch crystallization method according to claim 86, where the method comprises the additional step of selecting at least one of the crystallization buffers that characterizes the series of different micro-batch crystallization solutions by screening various potential buffers for their ability to crystallize the antibody using a vapor diffusion crystallization method.

88. (Previously Presented) The large-batch crystallization method according to claim 86 or 87, wherein said method produces crystals within twenty-four hours.

89. (Previously Presented) The large-batch crystallization method according to claim 86 or 87, wherein said method produces an antibody crystal having substantially similar properties as the corresponding uncryallized antibody in at least one of the following assays: SDS-PAGE (non-reducing conditions), SDS-PAGE (reducing conditions), HPLC gel filtration, dynamic light scattering, peptide mapping, N-terminal sequencing, monosaccharide

constitution, oligosaccharide profiling, bioassay (direct cytotoxicity) and bioassay (induced complement dependent toxicity).

90. (Previously Presented) The large-batch crystallization method according to claim 86 or 87, wherein the antibody is Infliximab.

91. (Currently Amended) An antibody crystal produced by the large-batch crystallization method according to any one of claims 86 to 90 and 92 to 93.

92. (New) A large-batch crystallization method for crystallizing an antibody comprising the following steps:

- a. preparing a series of different micro-batch crystallization solutions each of a total volume of at least 75 μ l, each solution comprising the antibody and a different crystallization buffer;
- b. crystallizing the antibody from each of the micro-batch crystallization solutions;
- c. selecting a micro-batch crystallization solution from the series of solutions that produces antibody crystals of good quality and yield;
- d. preparing a large-batch crystallization solution comprising the antibody and the crystallization buffer that characterized the selected micro-batch crystallization solution; and

e. agitating the large-batch crystallization solution for between about 3 and about 48 hours at a temperature between about -21°C and about 61°C, to produce antibody crystals.

93. (New) A large-batch crystallization method for crystallizing an antibody comprising the following steps:

- a. preparing a series of different micro-batch crystallization solutions each of a total volume of at least 100µl, each solution comprising the antibody and a different crystallization buffer;
- b. crystallizing the antibody from each of the micro-batch crystallization solutions;
- c. selecting a micro-batch crystallization solution from the series of solutions that produces antibody crystals of good quality and yield;
- d. preparing a large-batch crystallization solution comprising the antibody and the crystallization buffer that characterized the selected micro-batch crystallization solution; and
- e. agitating the large-batch crystallization solution for between about 3 and about 48 hours at a temperature between about -21°C and about 61°C, to produce antibody crystals.

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94. (New) Infliximab crystals produced by the large-batch crystallization method according to any one of claims 86-89 and 92-93.